Health Canada Santé Canada

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Health Product InfoWatch

October 2017

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REPORTING ADVERSE REACTIONS

Canada Vigilance Program
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HEALTH PRODUCTS MENTIONED IN THIS ISSUE

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This monthly publication is intended primarily for healthcare professionals and includes information on pharmaceuticals, biologics, medical devices and natural health products. It provides a summary of key health product safety information published in the previous month by Health Canada, as well as a selection of new health product safety information meant to raise awareness. New information contained in this issue is not comprehensive but rather represents a selection of clinically relevant items warranting enhanced dissemination.

CANADA 150

Canada

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of health product advisories, type I recalls as well as summaries of completed safety reviews published in September 2017 by Health Canada.

Apo-Nitroglycerin sublingual spray Advisory	Apotex Inc. recalled one lot (lot 6G07) of its Apo-Nitroglycerin sublingual spray (0.4 mg/metered dose) as the spray pump may malfunction and not deliver the drug.
Atypical antipsychotics Summary Safety Review	This safety review evaluated the risk of sleep walking and sleep-related eating disorder (SRED) associated with atypical antipsychotics (aripiprazole, asenapine, clozapine, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone). Health Canada's safety review has found a link between sleep walking and SRED and the use of atypical antipsychotics. Health Canada has recommended to update the Canadian product monographs for all atypical antipsychotics to include these adverse reactions.
Invokana (canagliflozin) and Invokamet (canagliflozin and metformin) Health Professional Risk Communication	An approximately two-fold increased risk of surgical lower limb amputation has been observed in two long-term clinical studies in type 2 diabetes patients with established cardiovascular disease (CVD) or at least two risk factors for CVD treated with Invokana. Healthcare providers are reminded to follow established diabetes care practice guidelines in patients treated with canagliflozin. The Canadian product monographs of Invokana and Invokamet will be updated to reflect this safety information.
Levonorgestrel-releasing intrauterine systems Summary Safety Review	This safety review evaluated the risk of suppressed lactation associated with levonorgestrel-releasing intrauterine systems (Mirena, Jaydess and Kyleena). Health Canada's review concluded that there is currently limited evidence to suggest a link. Health Canada is considering updating the Canadian product monographs for these products to mention that cases of decreased breast milk production have been reported.
Solu-Medrol Act-O-Vial 40 mg Health Professional Risk Communication	Solu-Medrol Act-O-Vial 40 mg is the only formulation of methylprednisolone in Canada that contains bovine-sourced lactose as an excipient. Serious allergic reactions have been reported in patients allergic to cow's milk proteins who were treated with Solu-Medrol Act-O-Vial 40 mg. Solu-Medrol Act-O-Vial 40 mg is contraindicated in patients with a known or suspected hypersensitivity to cow's milk. The Canadian product monograph has been updated to reflect this new safety information.

Thermography devices Information Update	Health Canada reminded Canadians that thermograms (which use thermal imaging) are not a substitute for mammograms used for routine monitoring and screening for breast cancer. While thermography devices are available in Canada, these devices have not been licensed in Canada to screen for breast cancer.
Unauthorized health products Advisory	Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have been selected to raise awareness and, in some cases, to stimulate reporting of similar adverse reactions.

PRODUCT MONOGRAPH UPDATES

The following safety labelling updates, which were recently made to the Canadian product monograph, have been selected for your awareness. A complete list of safety labelling updates for brand name pharmaceutical drugs is available on Health Canada's Web site.

Erythrocin I.V. (erythromycin lactobionate)

The concomitant use of Erythrocin I.V. with HMG-CoA reductase inhibitors that are extensively metabolized by CYP3A4 is now **contraindicated**. This information has been included in the *Contraindications* section of the Canadian product monograph for Erythrocin I.V.

Key messages for healthcare professionals:[1]

- Erythrocin I.V. should not be used concomitantly with HMG-CoA reductase inhibitors that are extensively metabolized by CYP3A4 (lovastatin or simvastatin), due to the increased risk of myopathy, including rhabdomyolysis.

Reference

1. *Erythrocin I.V.(erythromycin lactobionate)* [product monograph]. Dublin (Ireland): Amdipharm Limited; 2017.

Mefloquine

A **checklist about the contraindications** to the use of mefloquine has been added to the *Contraindications* section of the Canadian product monograph to support healthcare professionals when they prescribe this medication. As well, the risk of **permanent dizziness, vertigo, tinnitus, and loss of balance** has been clarified in the *Patient Medication Information* section and in the patient *Information Wallet Card*.

Key messages for healthcare professionals:[1]

- The new checklist which is available in the Canadian product monograph for Mefloquine provides a brief guide to conditions that are contraindications to mefloquine chemoprophylaxis. It is designed to assist in determining the patient's eligibility for mefloquine chemoprophylaxis.
- Patients should be advised to consult a healthcare professional if any neurological and / or psychiatric symptoms occur during the prophylactic use of mefloquine as healthcare professionals may have to discontinue mefloquine and prescribe an alternative medicine for the prevention of malaria.

Key messages to convey to patients:[1]

- Serious mental and nervous system side effects may occur at any time while taking mefloquine, and in a small number of people, may last for months or years after stopping mefloquine. In some people, dizziness, vertigo, tinnitus, and loss of balance may become permanent.

Reference

1. *Mefloquine (mefloquine)* [product monograph]. Vaughan, (ON): AA Pharma Inc.; 2017

Proton Pump Inhibitors (PPIs): Dexilant (dexlansoprazole), Losec (omeprazole), Nexium (esomeprazole), Nexium 24 hr (esomeprazole), Panto IV* (pantoprazole sodium for injection), Pantoloc (pantoprazole sodium), Pariet (rabeprazole), Prevacid, Prevacid FasTab (lansoprazole), Tecta (pantoprazole magnesium), Vimovo (naproxen/esomeprazole)

Interference with laboratory tests has been updated in the *Warnings and Precautions*, *Drug Interactions* and *Action and Clinical Pharmacology* sections of the Canadian product monographs for PPIs.

Key messages for healthcare professionals:[1-10]

- During treatment with antisecretory drugs (e.g., PPIs), chromogranin A (CgA) increases due to decreased gastric acidity. Increased CgA levels may interfere with investigations for neuroendocrine tumours.
- To avoid this interference, PPI treatment should be stopped 14 days before CgA measurements.

References

1. *Dexilant (dexlansoprazole)* [product monograph]. Oakville (ON): Takeda Canada Inc.; 2017.
2. *Losec (omeprazole)* [product monograph]. Mississauga (ON): AstraZeneca Canada Inc.; 2017.
3. *Nexium (esomeprazole)* [product monograph]. Mississauga (ON): AstraZeneca Canada Inc.; 2017.
4. *Nexium 24 hr (esomeprazole)* [product monograph]. Mississauga (ON): Pfizer Canada Inc.; 2017.
5. *Panto IV* (pantoprazole sodium for injection)* [product monograph]. Oakville (ON): Takeda Canada Inc.; 2017.
6. *Pantoloc (pantoprazole sodium)* [product monograph]. Oakville (ON): Takeda Canada Inc.; 2017.
7. *Pariet (rabeprazole)* [product monograph]. Toronto (ON): Janssen Inc.; 2017.
8. *Prevacid, Prevacid FasTab (lansoprazole)* [product monograph]. Deerfield (Illinois): Takeda Pharmaceuticals America, Inc.; 2017.
9. *Tecta (pantoprazole magnesium)* [product monograph]. Oakville (ON): Takeda Canada Inc.; 2017.
10. *Vimovo (naproxen/esomeprazole)* [product monograph]. Mississauga (ON): AstraZeneca Canada Inc.; 2017

*The PANTO IV (pantoprazole for injection, 40 mg/vial) DIN has been cancelled as of February 27, 2017. While Takeda Canada Inc. has stopped sale of the product, other parties in the distribution chain such as wholesalers, retailers, pharmacists and medical practitioners may still sell or distribute the remaining stock until the expiry date of March 31, 2018 for the last manufactured lot (#3364321). Generic versions of this drug product and dosage form are available on the Canadian market.

HELPFUL LINKS

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- Summary Safety Reviews
- New Safety Reviews
- Canada Vigilance Adverse Reaction Online Database
- Drug Product Database
- Medical Devices Active Licence Listing
- Licensed Natural Health Products Database
- The Drug and Health Product Register
- Drug Shortages Canada

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at InfoWatch_InfoVigilance@hc-sc.gc.ca

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Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Due to time constraints relating to the production of this publication, information published may not reflect the most current information.

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